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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,075	08/22/2003	Vijaya Juturu	NUTRI.027A	9604

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,075	JUTURU ET AL.	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-35 and 65-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-35 and 65-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/29/03 & 4/26/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 32-35 AND 65-68 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment and Response to Restriction Requirement filed August 27, 2004 has been received and entered into the application. Accordingly, claims 1-31 and 36-64 have been canceled.

Election/Restriction

As per the Restriction Requirement set forth in the previous Office action, applicants have elected Group V, claims 32-35 and 65-68. Insofar as no arguments have been presented, this election is taken without traverse. Also, because applicants have canceled all claims directed to the non-elected inventions, the requirement for restriction is rendered moot.

Applicants are advised that if claims 40-47, i.e., Group VII, had not been canceled, the Examiner, as per the previous Office action at page 3, first paragraph, would have examined claims 40-47 to the extent that they read on those diseases encompassed by the elected invention.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-35 and 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of McCarty et al. (U.S. Patent No. 5,707,970) in view of Speck (U.S. Patent No. 6,066,659), Harrison's Principles of Internal Medicine ("Harrison's") and Levere et al. (U.S. Patent No. 5,217,997).

It should be noted that the Examiner believes that the treatment of abnormal liver lipid concentrations (claim 33) is not taught or suggested by the references and thus is not considered in the following determination of obviousness.

McCarty et al. teaches the administration of an arginine silicate inositol complex in a dosage of between about 250 mg and about 2,500 mg for the treatment of atherosclerosis or for supplying a source of the essential amino acid arginine (col. 2, lines 33-43 and line 66 – col. 3, line 2 and col. 3, lines 34-36). It is further taught that the complex may be administered either intravenously, i.e., parenterally, or orally (col. 3, lines 48-50) to the individual.

The differences between the above and the claimed subject matter lay in that neither McCarty et al. reference highlights:

(1) "Treating a disease secondary to coronary vascular disease" (claim 33) such as nephrosclerosis, microvascular complications and macrovascular complications (claim 33) or "promoting cardiovascular health in an individual" (claim 65); and

(2) The claimed dosage amounts (claims 35 and 67).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(1) Speck teaches atherosclerosis to be a disease of the coronary vascular system which may lead to death (col. 1, lines 18-24). The skilled artisan would have appreciated that the treatment of atherosclerosis, as taught by McCarty et al. above, would be effective for "treating a disease secondary to coronary vascular disease" because atherosclerosis would be considered a coronary vascular disease and it would have logically flowed that by effectively treating such a disease, those diseases secondary to atherosclerosis could be prevented from occurring or else effectively ameliorated. Speck also teaches that atherosclerosis can lead to reduced perfusion of the extremities or brain infarct (col. 3, lines 23-24) which would be appreciated as involving microvascular/macrovascular complications as required by the present claims. Further, the skilled artisan would have appreciated that the atherosclerosis treatment of McCarty et al. would result in "promoting cardiovascular health in an individual" because atherosclerosis is a disease of the cardiovascular system and it logically flows that the effective treatment of such a disease is a manner of promoting health to that system.

As evinced by claim 33, claim 32 reads on the treatment of nephrosclerosis. The skilled artisan would have appreciated that the arginine silicate inositol complex of McCarty et al. could be used to treat nephrosclerosis because (a) Harrison's teaches that the major goal of therapy for nephrosclerosis is the control of hypertension (page 1321, column 2, second full paragraph) (b) as noted above, McCarty et al. teach that the arginine silicate inositol complex is a useful source

of arginine and (c) Levere et al. teach that arginine may be used to treat hypertension (see, for example, the abstract).

(2) McCarty teaches that the dosage may be between about 250 mg and about 2,500 mg and the optimum dosage to employ would have been expected to vary depending on, among other factors, the weight of the patient and as such, the dosages claimed, i.e., about 2 mg/kg body weight to about 2,500 mg/kg, are not seen to be outside those dosages that would have been determined by the skilled artisan.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Obviousness-Type (common assignee)

Claims 32-35 and 65-68 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-12 of U.S. Patent No. 5,707,970 (McCarty et al. '970) or claims 8-12 of U.S. Patent No. 6,156,735 (McCarty et al. '735) in view of Speck (U.S. Patent No. 6,066,659), Harrison's Principles of Internal Medicine ("Harrison's") and Levere et al. (U.S. Patent No. 5,217,997).

McCarty et al. '970 and '735 claim the oral or parenteral administration of an arginine silicate inositol complex in a dosage of between about 250 mg and about 2,500 mg for the treatment of atherosclerosis and teach (reliance upon disclosed but not claimed subject matter is proper where the reference is prior art) such administration also for supplying a source of the essential amino acid arginine (see, for example, col. 2, line 66 – col. 3, line 2 and col. 3, lines 34-36 of McCarty et al. '970).

The differences between the above and the claimed subject matter lay in that neither McCarty et al. reference highlights:

(1) "Treating a disease secondary to coronary vascular disease" (claim 33) such as nephrosclerosis, microvascular complications and macrovascular complications (claim 33) or "promoting cardiovascular health in an individual" (claim 65); and

(2) The claimed dosage amounts (claims 35 and 67).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(1) Speck teaches atherosclerosis to be a disease of the coronary vascular system which may lead to death (col. 1, lines 18-24). The skilled artisan would have appreciated that the treatment of atherosclerosis, as taught by McCarty et al. above, would be effective for "treating a disease secondary to coronary vascular disease" because atherosclerosis would be considered a coronary vascular disease and it would have logically flowed that by effectively treating such a disease, those diseases secondary to atherosclerosis could be prevented from occurring or else effectively ameliorated. Speck also teaches that atherosclerosis can lead to reduced perfusion of

the extremities or brain infarct (col. 3, lines 23-24) which would be appreciated as involving microvascular/macrovascular complications as required by the present claims. Further, the skilled artisan would have appreciated that the atherosclerosis treatment of McCarty et al. would result in "promoting cardiovascular health in an individual" because atherosclerosis is a disease of the cardiovascular system and it logically flows that the effective treatment of such a disease is a manner of promoting health to that system.

As evinced by claim 33, claim 32 reads on the treatment of nephrosclerosis. The skilled artisan would have appreciated that the arginine silicate inositol complex of McCarty et al. could also be used to treat nephrosclerosis because (a) Harrison's teaches that the major goal of therapy for nephrosclerosis is the control of hypertension (page 1321, column 2, second full paragraph) (b) as noted above, McCarty et al. teach that the arginine silicate inositol complex is a useful source of arginine and (c) Levere et al. teach that arginine may be used to treat hypertension (see, for example, the abstract).

(2) Both McCarty '970 and '735 claim that the dosage may be between about 250 mg and about 2,500 mg and the optimum dosage to employ would have been expected to vary depending on, among other factors, the weight of the patient and as such, the dosages claimed, i.e., about 2 mg/kg body weight to about 2,500 mg/kg, are not seen to be outside those dosages that would have been determined by the skilled artisan.

None of the claims are allowed.

The references cited on the attached form PTO-892 and not relied upon are included to show the general state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

September 22, 2004